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Medicaid Policy Number (This number will be generated by Medical Services.)

NDMP-2012-0004

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Title

**Cochlear Implants and Auditory Osseointegrated Implants** 

**Effective Date** 

10/1/2014

Revision Date(s)

06/15/2015

Replaces

**Cross References** 

#### Description

Cochlear Implants are devices that replace the function of the cochlear structures and provide electrical energy to auditory nerve fibers. It requires a surgically placed internal device and external hardware. Cochlear implantation may be an option to improve communication skills for persons with severe to profound hearing loss who receive limited or no benefit from hearing aids.

Hearing loss is described as conductive, sensorineural, or mixed and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech-Language-Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (>80 dB).

The auditory osseointegrated system has both implanted and external components. The implanted component is a small post that is surgically attached to the skull bone behind the ear. The external component is a speech processor which converts sound into vibrations; it connects to the implanted post and transmits sound vibrations directly to the inner ear through the skull, bypassing the middle ear.

### Scope

ND Medicaid reimburses cochlear implants and auditory osseointegrated implants when there is documentation to demonstrate that the procedure is medically necessary and would be beneficial in reducing the limitations of the hearing impairment.

Prior authorization of the surgery and device must be received by the Medical Services department prior to the procedure taking place using Medical Procedure/Device Prior Authorization Request Form - SFN511 at: <a href="http://www.nd.gov/eforms/Doc/sfn00511.pdf">http://www.nd.gov/eforms/Doc/sfn00511.pdf</a> . This form must be completed in its entirety and all applicable documentation must be attached.

#### **Policy**

Cochlear implantation and auditory osseointegrated implants must be used in accordance with the FDA approved labeling.

## **Policy Guidelines**

#### **Unilateral Cochlear Implantation Criteria:**

 The recipient must have a diagnosis of bilateral severe to profound sensorineural hearing loss with limited benefit from appropriate hearing aids for ages 24 months and older. ND Medicaid recipients 12 through 23 months old must experience a bilateral profound hearing loss.

- Limited benefit demonstrated from appropriately fitted hearing aids with consistent use over a 3-6 month time period. The trial period may be waived or shortened with appropriately submitted documentation of medical necessity.
- Evidence of a functioning auditory nerve.
- Freedom from middle ear infection
- An accessible cochlear lumen structurally suited to implantation.
- No evidence of lesions in the auditory nerve and acoustic areas of the central nervous system. This may be demonstrated by CT scan or other appropriate radiological evaluation.
- No contraindication to anesthesia/surgery
- Cognitive ability to use auditory clues and demonstrate a conditioned response
- Psychological development, motivation of the candidate, and/or commitment of the beneficiary and family caregivers to undergo a program of prosthetic fitting, training and long term rehabilitation.
- The device must be used in accordance with the FDA approved labeling.

### **Bilateral Cochlear Implantation Criteria:**

ND Medicaid covers bilateral cochlear implantation when there is documentation that demonstrates the procedure is medically necessary and would be beneficial in reducing limitation of hearing impairment. Bilateral cochlear implantation must meet all of the criteria for unilateral cochlear implantation, above, in addition to the following criteria and circumstances:

- Simultaneous bilateral cochlear implants
- 1. Have significant deafness caused by meningitis with subsequent risk for early cochlear ossification, and, in the opinion of the treating physician, are appropriate candidates for bilateral cochlear implantation for the syndrome of post-meningitis deafness prior to cochlear ossification, **OR**
- 2. Pre-lingually deaf children with profound hearing loss, and who, in the opinion of the treating specialist physician, would benefit from the additional neuronal stimulation afforded by simultaneous bilateral cochlear implantation at an early age. Some patients in this category may, in the opinion of the treating specialist physician, benefit from a staged or subsequent contralateral cochlear implantation as opposed to a simultaneous implantation.
- Subsequent contralateral cochlear implantation in patient who have already received a previous unilateral cochlear implant
- 1. Have bilateral profound deafness that have fallen short of communication goals despite prior placement of a unilateral cochlear implant, and in the opinion of the treating specialist physician, would substantially benefit from a subsequent contralateral cochlear implant,
- 2. Are pre-lingually deaf children with bilateral profound hearing loss who have had prior unilateral cochlear implantation and who, in the opinion of the treating specialist physician, would substantially benefit from a subsequent contralateral cochlear implant, **OR**
- 3. Have bilateral auditory neuropathy to the extent such that their cochlear function is structurally normal but who have abnormal findings on auditory brainstem response testing, and, in the opinion of the treating specialist physician, would substantially benefit from a subsequent contralateral cochlear implant.

ND Medicaid does not cover for bilateral cochlear implantation, either as a simultaneous procedure or a subsequent contralateral implantation if, in the opinion of the treating physician, audiologist, or therapist, the beneficiary has sufficient limited hearing in the lesser affected ear could be:

Sufficiently augmented by a hearing aid to augment the opposite cochlear implant

### **Auditory Osseointegrated Implants**

ND Medicaid will reimburse the least costly alternative that meets the recipient's medical need for medical supplies, durable medical equipment, or orthotics/prosthetics. One (unilateral) auditory osseointegrated device will be covered per recipient. A second (bilateral) is not a covered benefit.

- A. ND Medicaid will reimburse auditory osseointegrated devices with a unilateral or bilateral conductive or mixed conductive and sensorineural hearing loss, where the condition prevents restoration of hearing using a conventional air-conductive hearing aid when the following criteria are met:
- 1. Use of an FDA approved device in accordance with its recommended use.
- 2. The recipient must be 5 years of age or older to qualify for surgically implanted components.
- 3. Beneficiary must have one of the following conditions:
  - Congenital malformations of the middle/external ear or microtia.
  - Severe chronic otitis externa and/or chronic suppurative otitis media with chronic drainage preventing use of conventional air-conduction hearing aids.
  - Conductive loss due to ossicular disease and not appropriate for surgical correction.
  - Tumors of the external ear canal and or tympanic cavity.
  - Unilateral sensorineural hearing loss (single sided deafness).

\*Conditions not meeting these criteria are considered investigational/experimental and are not covered.

### B. Audiological Criteria

- 1. Unilateral or Bilateral conductive or mixed hearing loss:
  - Puretone average bone conduction thresholds better or equal to 70 dB HL in ear to be implanted.
  - A speech recognition score better than 60% using appropriate speech recognition testing.
- 2. Unilateral profound sensorineural hearing loss:
  - Confirmed profound hearing loss (greater than 90 dB HL) in one ear with the confirmed bone conduction thresholds in the opposite ear of 40 dB HL or better.
- C. Osseointegrated device, external sound processor, used without osseointegration (Soft band device without surgically implanted components)

This device will be covered for recipient who meets the above criteria but have either not reached the age of 5 years or are not appropriate surgical candidates. <u>Prior authorization is required</u>. The soft band device is not covered for unilateral sensorineural hearing loss (single sided deafness). The documentation requirements for soft band without surgical components are:

- Complete audiology studies that define the type and degree of hearing loss in each ear.
- Audiology report with history of hearing aid use and documentation of inability to use an air conduction hearing aid.
- Letter from surgeon stating medical need.

### **Benefit Application**

ND Medicaid does not reimburse the cost of the implant device through the Durable Medical Equipment (DME) program. The cost of the device is covered by the usual reimbursement methodology for either inpatient or outpatient hospital services and must be billed by the hospital. ND Medicaid does not cover additional benefits for the device if the surgical procedure is performed in any other outpatient setting.

The device should be billed under revenue code 278 with the applicable HCPCS code for the device. Please view ND Medicaid's Policy for Revenue code 278 - Supply/Other Implants at:

http://www.nd.gov/dhs/services/medicalserv/medicaid/docs/rev-code-278-policy.pdf.

ND Medicaid covers the repair and/or replacement of the cochlear implant external speech processor and other minor supplies including batteries, cords, battery charger, and headsets through the Durable Medical Equipment (DME) program. ND Medicaid covers these items for all recipients by DME providers only. ND Medicaid requires prior approval for repairs or replacements of external implant parts. Please refer to the ND Medicaid DME Provider Manual for specific information regarding limits of coverage of cochlear implant and auditory osseointegrated implant supplies. The manual can be found at: http://www.nd.gov/dhs/services/medicalserv/medicaid/docs/dme/dme-manual.pdf.

All ND Medicaid policies and procedures for specific program areas still apply in addition to the limits of this policy. Out of State rules and regulations must be met before this policy becomes effective. Equipment and devices will not be replaced due to cosmetic preferences or technology upgrades. Damage due to maltreatment, misuse and/or tampering by the recipient is the responsibility of the recipient. If equipment is in working condition when devices are eligible for replacement, ND Medicaid has the right to refuse replacement due to lack of medical necessity.

#### **Rationale Source**

- Milliman Care Guidelines©, Ambulatory Care, 15th Edition. 2011 Milliman Care Guidelines LLC, 9/19/11 update.
   www.careguidelines.com
- Blue Cross North Dakota Medical Policy, 2011 Update
- Blue Cross Minnesota Medical Policy, 2011Update
- Minnesota HealthPartners Medical Policy, 2011Update
- National Coverage Determination for Medicare and Medicaid, 2005 Update
- Centers for Medicare & Medicaid (CMS). National Coverage Determination (NCD) Pub. 100.3, section 310.1
   Cochlear Implantation. Available at: <a href="https://www.cms.hhs.gov">www.cms.hhs.gov</a>
- British Cochlear Implant Group (BCIG). Position Statement Bilateral Cochlear Implantation. May 2007. Revised May 2008. Accessed September 2009. Available at:
   <a href="http://www.bcig.org.uk/downloads/pdfs/BCIG%20position%20statement%20-%20Bilateral%20Cochlear%20Implantation%20May%2007.pdf">http://www.bcig.org.uk/downloads/pdfs/BCIG%20position%20statement%20-%20Bilateral%20Cochlear%20Implantation%20May%2007.pdf</a>.
- BadgerCare Plus and Medicaid, Cochlear Implant and Bone-Anchored Hearing Aid Surgeries. 1/28/2013
- <a href="http://dhcfp.nv.gov">http://dhcfp.nv.gov</a> ; Hearing Aid Dispenser and Related Supplies and Audiology Services, Nevada Medicaid; updated 01/03/2013
- Michigan Department of Community Health; Coverage of Cochlear Implants and Auditory Osseointegrated Implants
- Mississippi Medicaid; Title 23:Medicaid Part 218 Hearing Services
- Clinical Policy Bulletin: Bone-anchored Hearing Aid; www.aetna.com; 07/27/2012
- Bone Anchored Hearing Aid(BAHA); <u>www.medica.com</u>; 12/1/2010

# Code of Federal Regulations Citation(s)

42 CFR 405.201

CODES	NUMBER	DESCRIPTION
CPT <sup>®</sup>	69714	Implantation, osseointegrated implant, temporal bone, with percutaneous
		attachment to external speech processor/cochlear stimulator, without
		mastoidectomy
	69715	Implantation, osseointegrated implant, temporal bone, with percutaneous
		attachment to external speech processor/cochlear stimulator, with mastoidectomy
	69717	Replacement (including removal of existing device), osseointegrated implant,
		temporal bone, with percutaneous attachment to external speech processor/cochlear
		stimulator, without mastoidectomy
	69718	Replacement (including removal of existing device) osseointegrated implant, temporal
		bone, with percutaneous attachment to external speech processor/cochlear
		stimulator, with mastoidectomy
	69930	Cochlear device implantation, with or without mastoidectomy
	92606	Therapeutic service(s) for the use of non-speech generating device, including programming and modification

Applicable Modifier(s)	50	Bilateral procedure
,	RT	Right side
	LT	Left side
ICD-9 Procedures(s)	20.95	Implantation of electromagnetic hearing device
. 100044100(0)	20.96	Implantation or replacement of cochlear prosthetic device, not otherwise specified
	20.97	Implantation or replacement of cochlear prosthetic device, single channel
	20.98	Implantation or replacement of cochlear prosthetic device, multiple channel
ICD-10 Procedures(s)	09HD04Z	Insertion of Bone Conduction Hearing Device into Right Inner Ear, Open Approach
	09HD34Z	Insertion of Bone Conduction Hearing Device into Right Inner Ear, Percutaneous Approach
	09HD44Z	Insertion of Bone Conduction Hearing Device into Right Inner Ear, Percutaneous Endoscopic Approach
	09HE04Z	Insertion of Bone Conduction Hearing Device into Left Inner Ear, Open Approach
	09HE34Z	Insertion of Bone Conduction Hearing Device into Left Inner Ear, Percutaneous Approach
	09HE44Z	Insertion of Bone Conduction Hearing Device into Left Inner Ear, Percutaneous Endoscopic Approach
	0NH50SZ	Insertion of Hearing Device into Right Temporal Bone, Open Approach
	0NH53SZ	Insertion of Hearing Device into Right Temporal Bone, Percutaneous Approach
	0NH54SZ	Insertion of Hearing Device into Right Temporal Bone, Percutaneous Endoscopic Approach
	0NH60SZ	Insertion of Hearing Device into Left Temporal Bone, Open Approach
	0NH63SZ	Insertion of Hearing Device into Left Temporal Bone, Percutaneous Approach
	0NH64SZ	Insertion of Hearing Device into Left Temporal Bone, Percutaneous Endoscopic Approach
	09HD0SZ	Insertion of Hearing Device into Right Inner Ear, Open Approach
	09HD3SZ	Insertion of Hearing Device into Right Inner Ear, Percutaneous Approach
	09HD4SZ	Insertion of Hearing Device into Right Inner Ear, Percutaneous Endoscopic Approach
	09HE0SZ	Insertion of Hearing Device into Left Inner Ear, Open Approach
	09HE3SZ	Insertion of Hearing Device into Left Inner Ear, Percutaneous Approach
	09HE4SZ	Insertion of Hearing Device into Left Inner Ear, Percutaneous Endoscopic Approach
	09HD05Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Open Approach
	09HD35Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Approach
	09HD45Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Endoscopic Approach
	09HE05Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Open Approach
	09HE35Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Approach
	09HE45Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Endoscopic Approach
	09HD06Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Open Approach
	09HD36Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Approach
	09HD46Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Endoscopic Approach
	09HE06Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Open Approach
	09HE36Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous

		Approach
	09HE46Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous
		Endoscopic Approach
ICD-9 Diagnosis(es)	389.00	Conductive hearing loss, unspecified
	389.01	Conductive hearing loss, external ear
	389.02	Conductive hearing loss, tympanic membrane
	389.03	Conductive hearing loss, middle ear
	389.04	Conductive hearing loss, inner ear
	389.05	Conductive hearing loss, unilateral
	389.06	Conductive hearing loss, bilateral
	389.08	Conductive hearing loss of combined types
	389.10	Sensorineural hearing loss, unspecified
	389.11	Sensory hearing loss, bilateral
	389.12	Neural hearing loss, bilateral
	389.13	Neural hearing loss, unilateral
	389.14	Central hearing loss
	389.15	Sensorineural hearing loss, unilateral
	389.16	Sensorineural hearing loss, asymmetrical
	389.17	Sensory hearing loss, unilateral
	389.18	Sensorineural hearing loss, bilateral
	389.20	Mixed hearing loss, unspecified
	389.21	Mixed hearing loss, unilateral
	389.22	Mixed hearing loss, bilateral
ICD-10	H90.0	Conductive hearing loss, bilateral
Diagnosis(es)		
	H90.11	Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
	H90.12	Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the
	H90.12	contralateral side
	H90.3	Sensorineural hearing loss, bilateral
	H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the
		contralateral side
	H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the
		contralateral side
	H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with
	1100.73	unrestricted hearing on the contralateral side  Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted
	H90.72	hearing on the contralateral side
	H90.6	Mixed conductive and sensorineural hearing loss, bilateral
Applicable Revenue Codes(s)	278	Other Implants/Supplies
	360	Operating Room Services - General Classification
	490	Ambulatory Surgical Care - General Classification
HCPCS Code(s)	L7520	Repair prosthetic device, labor component, per 15 minutes
( <del>)</del>	L7614	Cochlear device, includes all internal and external components
	L8615	Headset/headpiece for use with cochlear implant device, replacement
	L8616	Microphone for use with cochlear implant device, replacement
	L8617	Transmitting coil for use with cochlear implant device, replacement

	L8618	Transmitter cable for use with cochlear implant device, replacement
	L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
	L8621	Zinc air batter for use with cochlear implant device, replacement, each
	L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
	L8623	Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each
	L8624	Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each
	L8627	Cochlear implant, external speech processor, component replacement
	L8628	Cochlear implant, external controller component, replacement
	L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
	L8690	Auditory osseointegrated device, includes all internal and external components
	L8691	Auditory osseointegrated device, external sound processor, replacement
	L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of attachment
	V5266	Battery for use in hearing device
Type of Service		General Surgery
Place of Service	21 or 22	Inpatient Hospital or Outpatient Hospital

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The North Dakota Medicaid program adopts policies after careful review of published peer-review scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, North Dakota Medicaid reserves the right to review and update policies as appropriate. Always consult the General Information for Providers manual or North Dakota Medicaid Policy to determine coverage. CPT codes, descriptions and material are copyrighted by the American Medical Association.